UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 27 [illegible]3

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

TO: Michael Mendelson, Regulatory Action Leader
Biopesticide and Pollution Prevention Division, 7511C

FROM: Robyn Rose, Entomologist Robyn Rose
Biopesticide and Pollution Prevention Division, 7511C

PEER REVIEW: Sharlene Matten, Ph.D., Biologist
Biopesticide and Pollution Prevention Division, 7511C

THROUGH: Phil Hutton, Branch Chief 8018
Microbial Pesticides Branch
Biopesticide and Pollution Prevention Division, 7511C

SUBJECT: Amendment of EPA registration for MON 810 YieldGard™, *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn; EPA Reg. No. 524-489, DP Barcode No. 245250, Case No. 005562.

ACTION REQUESTED:
BPPD has been asked to review the specific terms and conditions associated with registration of Monsanto's MON 810 YieldGard Bt corn. Monsanto would like to substitute the 100,000 acre limitation, and the 5% sales limit per county, with on-farm refuges.

CONCLUSIONS:
The USDA NC205 (Ostlie et al, 1997; NC205 Supplement, October 1998) on lepidopteran pests of corn concluded that a 20-30% non-Bt refuge planted in close proximity to the *Bacillus thuringiensis* (Bt) corn field is necessary to decrease the potential of European corn borer (ECB, *Ostrinia nubilalis*) resistance to Bt. BPPD agrees with the NC205 refuge recommendations. Although the optimal size of the refuge is dependent upon many biological and economic factors, Hurley et al. (1997) concluded that the current recommendation of a 20-30% refuge is justified for ECB (*Biotechnology and pest resistance: an economic assessment of refuges*. Terrance M. Hurley, Bruce A. Babcock, and Richard L. Hellmich, study submitted by DEKALB).

In a 1997 report developed by Dr. Michael Caprio (submitted to the Agency by Novartis as part of their 1997 research) titled Interim Report, Corn-Cotton Ecosystem Model for Resistance Evolution in *Helicoverpa zea* to Bt-endotoxins Expressed in Plants, the author stated that "results suggest that some use of Bt-corn in the Mid-South is acceptable, though based on preliminary results the proportion should certainly not exceed 50%." The author further stated that as the ratio of non-Bt corn, in Bt cotton growing areas, decreases relative to Bt corn, the time to CEW resistance decreases. The effect was most pronounced when the ratio of the Bt to non-Bt corn was greater than 50%.

Caprio's model indicates that non-Bt corn should be planted with Bt corn especially in overlapping Bt corn and Bt cotton areas to avoid rapid evolution of CEW resistance. Therefore, based on Caprio's model, the Agency recommends planting non-Bt corn, as a structured refuge, with Bt corn (especially in Bt cotton growing areas) to avoid the quick evolution of CEW resistance. Work is ongoing to develop models to predict corn earworm resistance development in overlapping Bt corn and Bt cotton growing areas. Further research needs to occur in this area; especially regarding larval movement and impact on fitness, adult movement and mating, and overall population dynamics.

A communication written by Dr. Rick Weinzierl to the members of the NC205 was submitted to the Agency (September 1998). In the memo, Dr. Weinzierl recommended "requiring a larger-than-actually-needed refuge during the next few years while more data are gathered." Weinzierl suggests a conservative approach when determining refuge size and points out that a larger than necessary refuge will not cause dramatic losses, whereas a refuge that is too small may increase the potential loss of Bt crop technology. Current research has also shown that the risk of insect resistance to Bt can be reduced by planting a non-Bt refuge within 1500 to 2000 feet of the Bt corn (*Mark-recapture study examining adult European corn borer dispersal to and among attraction sites -year two of a three year study* T.E. Hunt, J.F. Witkowski, L.G. Higley, and R.L. Hellmich; work submitted by Novartis, Mycogen, Dekalb, and Monsanto).

BPPD, therefore, recommends substituting current southern restrictions on MON 810 Bt corn with a mandated structured refuge of 50% non-Bt corn, planted in blocks, that may be sprayed on a limited basis with non-Bt insecticides to control lepidopteran pests. The refuge should be planted within approximately 1/3 mile (~1500 ft) of the Bt corn field in all southern cotton growing areas. Unless Monsanto can present additional CEW overwintering data that justifies a refuge smaller than 50% in the northern cotton growing region, a 50% refuge is also necessary in the northern cotton growing areas. Monsanto should, therefore, expand on the submitted CEW overwintering, flight distance to mating, and behavior data to make a sound case for dividing the cotton growing region in two tiers; especially for certain counties in Arkansas, western Tennessee, and North Carolina. Since cotton is a preferred overwintering site for CEW, it is also recommended that Bt cotton fields be required to be plowed post harvest to destroy potentially overwintering CEW pupae.

Benefits of MON 810

MON 810 has been available for commercial production for two growing seasons; 1997 and 1998. During the 1997 growing season, MON 810 hybrids provided season-long control of the ECB and Southwestern corn borer (SWCB, *Diatraea grandiosella*) across the Central Corn Belt. Growers planting MON 810 in the Central Corn Belt yielded 10.8 Bu/acre (per acre dividend = $17) versus non-Bt hybrids during the 1997 growing; 1998 results from southeast cotton growing regions were similar. Research entomologists from the University of Maryland and Virginia Polytechnic Institute and State University observed MON 810 grown in close proximity to soybean decreased CEW infestations and thus podworm injury to soybean; this may be an example of the halo effect. In information cited by Monsanto, Dr. John Benedict of Texas A&M University suggested the same reduction in bollworm injury may occur if MON 810 is planted in close proximity to cotton (personal communication with Monsanto, 1998).

Dr. Galen Dively and Dr. John Van Duyn have shown that MON 810 reduces the mycotoxin fumonisin, aflatoxin in particular, compared to conventional hybrids. Benedict (1998 Unpublished data) attributes the reduction in mycotoxins to decreased kernel feeding and larval movement in MON 810. An additional benefit of MON 810 is the decrease in conventional chemical use thus decreasing environmental and worker exposure (Information provided in Monsanto's amendment request).

Grower Economic Issues

Information submitted by Monsanto stated that MON 810 was planted on [redacted] during the 1997 growing season and projections estimate that [redacted] were planted in 1998. According to a Monsanto survey, 90% of the growers planting MON 810 were satisfied and 81% will plant MON 810 again. Due to current sales restrictions in northern and southern cotton growing regions (100,000 acres of MON 810 may be grown in certain cotton growing regions), corn growers in these regions have had limited access to MON 810 corn. Monsanto also believes that data on performance of MON 810 in these regions has been limited due to the sales restriction. According to Monsanto, Pioneer (under a license issued by Monsanto to sell MON 810) has shown a yield advantage in the Central Corn Belt of 7.7 Bu/acre under low corn borer levels and 9.7 Bu/acre under high corn borer levels. They expect similar results if MON 810 is grown on more acres in the southeast cotton growing regions.

Pioneer projected refuge costs with low corn borer levels were: $1.85/acre with a 20% non-Bt refuge; $3.70/acre with a 40% non-Bt refuge; and $4.63/acre with a 50% refuge. Pioneer projected refuge costs with high corn borer levels were: $2.85/acre with a 20% non-Bt refuge; $5.70/acre with a 40% non-Bt refuge, and $7.13/acre with a 50% non-Bt refuge.

Risk of Resistance

According to Horner & Dively (1997) and Storer & Van Duyn (1998) MON 810 does not provide high efficacy for controlling CEW infesting ears, with relative mortality rates through pupation ranging from 70-85%. Dively et al (1998) completed three years of field trials in 1997

conducted in Maryland and Virginia to evaluate Yieldgard (Pioneer 33V08) against CEW. The number of CEW that completed development on Yieldgard and became reproductive adults was also evaluated. Results from this study provided insight into the risk of resistance development and the potential for area-wide suppression. It should be noted that this data on pupation and moth emergence came from late planted corn. The corn was planted late to ensure a high natural infestation of CEW. The late planting date is not typical in the mid Atlantic and early plantings may yield different results.

Infestation levels of CEW were reduced by an average of 25% in Bt corn and densities were reduced by 30%. Kernel damage was reduced by 71% in Bt ears when compared to non-Bt ears. No CEW developed beyond the fourth instar when feeding on silks and kernels expressing Bt. There was a greater number of late instar CEW larvae found in Yieldgard ears during later stage kernel development in 1997 than in 1996 and the number that survived to pupation was surprisingly high. This may have been due to egg laying pressure and larval development sustaining longer as the plants senesced or possibly due to decreased cannibalism. This is a concern because it increases the chance of resistance developing. Developmental time to pupation of prepupae collected from Yieldgard was decreased by 23%. Slowing developmental time increases the chance that the insect will be controlled by natural enemies. A slower developmental time may, however, cause potentially resistant insects to emerge subsequent to susceptible insects produced in the refuge. This could lead to non-random mating and increase the likelihood of CEW resistance.

During 1996 and 1997, CEW reared on Bt corn in the lab demonstrated slightly higher fecundity, laid approximately 1/3 fewer eggs per day, and were 33% less fecund than CEW reared on conventional corn. It should be noted that the test was conducted in the lab rather than the field, thus, overestimating effects due to a lack of natural mortality and environmental stress. Of the non-Bt prepupae introduced in cages in mid August, approximately 35% emerged within a week and 10% emerged from the Bt cages. Of the non-Bt prepupae introduced in August, 26% emerged as moths in late September, compared to no moths emerging from the Bt prepupae. If this high mortality rate of diapausing pupae occurs under typical field conditions, there could be a subsequent reduction in resistance risks by eliminating resistant alleles in the population. (Galen P. Dively, Tracy Horner, and D. Ames Herbert. 1998. *Impact of Bt endotoxin-expressing transgenic corn on corn earworm and its implications to resistance development and area-wide suppression*. Unpublished data submitted to the Agency by Monsanto and Novartis).

In a baseline susceptibility study of the CEW to CryIA(b), Siegfried et al. (1997 research report) observed significant growth inhibitions and EC_{50} values (range: 0.91-5.17 ng/cm^2) were determined for six populations. The CEW demonstrated low sensitivity to CryIA(b) showing a lack of a "high dose" (indicated by larval survival) for CEW observed in all of the Bt field corn events, including MON 810, expressing CryIA(b).

MON 810 Registration

According to the terms and conditions of Monsanto's MON 810 YieldGard® corn's registration,

combined sales in specific states and counties cannot exceed 100,000 acres annually and there can be no more than 5% of corn planted in any county with more than 1,000 acres of cotton. These restrictions were implemented due to concerns of potential CEW developing resistance to Cry IA(b) and Cry IA(c) especially in areas where Bt corn and Bt cotton overlap. CEW, a pest of corn, is also commonly known as the cotton bollworm (CBW) and is a major pest of cotton.

Based upon research and recent results from spatial computer simulation models conducted by leading academics, Monsanto believes that the current southern restrictions are overly conservative. Monsanto has, therefore, requested an amendment to MON 810's registration that would revoke sales restrictions in the South. They would like to substitute mandated refuges in the South for the current restrictions. Monsanto proposes that farmers plant a required minimum of 50% of their corn acreage to non-Bt corn that can be treated with non-Bt insecticides to control lepidopteran insect pests in southern cotton growing regions[1] including Texas, southern Arkansas, Louisiana, Mississippi, Alabama, Georgia, South Carolina, and Florida. In northern cotton growing regions[2] including northern Texas (excluding ten Panhandle counties), northern Arkansas, North Carolina, and currently restricted counties in Missouri, Oklahoma, Tennessee, and Virginia, Monsanto proposed a minimum on-farm refuge of 20% unsprayed or 40% sprayed with non-Bt insecticides.

[1]Southern cotton growing regions:

Alabama- all counties; Arkansas- counties of Arkansas, Ashley, Bradley, Calhoun, Chicot, Clark, Cleveland, Columbia, Dallas, Desha, Garland, Grant, Hempstead, Hot Spring, Howard, Jefferson, Lafayette, Lee, Lincoln, Little River, Lonoke, Miller, Monroe, Montgomery, Nevada, Oachita, Phillips, Pike, Polk, Prairie, Pulaski, Saline, Sevier, and Union; Florida, Georgia, Louisiana, Mississippi, and South Carolina- all counties; Texas- all counties except Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Collingsworth, Cottle, Dallam, Deaf Smith, Donley, Floyd, Foard, Gray, Hale, Hall, Hansford, Hardeman, Hartley, Hemphill, Hutchinson, Lamb, Lipscomb, Moore, Motley, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Swisher, Wheeler, Wichita, and Wilbarger.

[2]Northern cotton growing regions:

Arkansas- counties of Baxter, Benton, Boone, Carroll, Clay, Cleburne, Conway, Craighead, Crawford, Crittenden, Cross, Faulkner, Franklin, Fulton, Greene, Independence, Jackson, Johnson, Izard, Lawrence, Logan, Madison, Marion, Mississippi, Newton, Perry, Poinsett, Pope, Randolph, Scott, Searcy, Sebastian, Sharp, St. Francis, Stone, Van Buren, Washington, White, Woodruff, and Yell; Missouri- bootheel counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard; Oklahoma- counties of Bryan, Caddo, Canadian, Garvin, Grady; North Carolina- all counties; Tennessee- counties of Carroll, Chester, Crockette, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, and Tipton; Texas- Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Collingsworth, Cottle, Deaf Smith, Donley, Floyd, Foard, Gray, Hale, Hall, Hardeman, Lamb, Motley, Oldham, Parmer, Potter, Randall, Swisher, Wheeler, Wichita, Wilbarger; Virginia- counties of Greensville, Isle of

Wight, Northhampton, Southhampton, Sussex, and Suffolk.

REVIEW OF SCIENTIFIC SUPPORT FOR REFUGE REQUIREMENTS:

Spray Options

Monsanto has presented data on current spraying practices for the ECB and SWCB. These data show, particularly in western regions of the South, a significant number of corn acres are treated for corn borers. But, according to Monsanto, few acres in southern cotton growing regions are sprayed for CEW or corn borers. Only a small percentage of corn acres are sprayed for CEW in southern cotton growing regions because of low economic returns and spraying must occur when adults are present to be effective. Since second and third generation ECB and SWCB typically occur after silking, insecticide applications would have limited impact on the survival rate of CEW. Monsanto anticipates relatively few growers will choose a sprayed option for corn borer control because very few acres (<6%) are treated with insecticides in the southeastern cotton growing region. Rather than recommend an unsprayed and sprayed option, Monsanto recommends one sprayed refuge option for southern cotton growing regions that they do not expect will be sprayed with insecticides on a routine basis. A sprayed refuge option is recommended for the southern cotton growing regions to allow treatments if a situation occurs where it is needed. Monsanto does recommend a 20% non-sprayed refuge option and a 40% sprayed refuge option be available to growers in northern cotton growing regions.

Monsanto's Basic Points

Monsanto proposes a 50% non-Bt refuge that can be sprayed with insecticides for stalk boring insects in southern cotton growing regions. They cite the following points to support their request: 1. There is a higher Bt cotton penetration (~70% in Alabama) in this area; 2. There is a higher rate of CEW overwintering survival this region; 3. 100% of the growers will not plant MON 810 and other corn varieties will be planted in this area; 4. Storer's model showed that a refuge ≤50% would be sufficient to delay resistance for ten years in region of high Bt cotton penetration; 5. Few growers would choose a sprayed refuge option since few growers currently spray for CEW or corn borers; 6. Economic projections and grower surveys show a need for MON 810 in this region; 7. Since CEW overwinter in cotton fields, post harvest tillage will reduce CEW survival (e.g. bollweevil eradication program).

Monsanto proposes a 20% unsprayed non-Bt refuge or a 40% refuge that can be sprayed with insecticides to control stalk boring pests in northern cotton growing regions. They cite the following points to support their request: 1. CEW and SWCB are key pests in this region; 2. Field performance of MON 810 against SWCB was similar to performance against ECB. There is, therefore, probably a high dose for SWCB; 3. There is an increased risk of resistance in this region because there are three ECB generations per year. The 20% unsprayed, 40% sprayed refuge option is, therefore, recommended; 4. There is not a high dose in MON 810 against the CEW; 5. There is low adoption of Bt cotton in this region. Most counties grow less than 10% Bt cotton; 6. CEW overwintering survival in this area is 0-5%; 7. Although there is not a high dose for CEW, Storer's model suggests that resistance will be delayed ten years (40 generations) in areas of low Bt cotton penetration (≤20%); 8. Since corn acreage in this region exceeds 40%,

Mon 810 and Corn Earworm

The CEW is a polyphagous insect that may change hosts during a growing season and completes two to five generations per year. The first generation develops on wild hosts or whorl stage corn, the second generation develops on ear-stage corn, and the third and fourth generation generally develop primarily on cotton (Storer et al., Appendix 1). Overwintering mortality accounts for 96.6% pupal mortality; all other stages suffer 100% overwintering mortality (Storer et al, Appendix 1). Monsanto also reported that cotton fields are a preferred overwintering site for CEW and studies have shown that post harvest plowing of cotton fields destroys CEW pupae. Monsanto also states that the CEW may move up to 50 km. Monsanto does not, however, document where they acquired this information nor do they state the average distance a CEW will move to mate. CEW do not always leave the field to mate, thus, non-random mating may still occur.

Although CEW are not major pests in corn, corn provides a habitat for CEW until they shift to soybean or cotton where they cause considerable damage later in the season. Based on the 1997 IRM research reports submitted to the Agency by the registrants (Monsanto, Dekalb, Novartis, Mycogen), it can be concluded that there is not a high dose of Bt expressed to control the CEW in any of the Bt corn events tested. MON 810 is expressed in the ear and silk tissue and is biologically active against CEW larvae. MON 810 hybrids did exhibit significantly greater levels of protection when compared to their non-Bt counterpart. CEW feeding on ears demonstrated approximately 70-85% mortality (Dively & Horner, 1997; Storer & Van Duyn, 1998).

Monsanto presents results from a model composed by Storer et al. (Appendix 1). According to this model, areas where ≤20% Bt cotton is planted, resistance would take ≥10 years or 40 generations to develop assuming Bt corn penetration does not exceed 90%. In areas that 50 to 75% Bt cotton is planted, resistance could be delayed ≥10 years if Bt corn is restricted to 50% of the corn acres. Unfortunately this model is basing results on delaying resistance for ten years; this isn't long enough. This model also makes assumptions regarding Bt cotton market penetration and only includes parameters from two states (North Carolina and Maryland). The acreage of Bt corn planted in the US has increased at a greater rate than originally estimated by the Agency in 1995. The Agency expected approximately 5% of the total corn acres would be planted with Bt corn in the first three years of commercial distribution. In 1997, after only two years of commercial distribution, 4.4 million acres, or 6%, of the total corn acres were planted in Bt corn. It is expected that in 1998 the Bt corn acreage will be greater than twice the Bt corn acreage planted in 1996; 1999 Bt corn acreage is expected to be greater than 1998. In addition, preliminary 1998 Bt cotton sales data indicate that Bt cotton acres in parts of the northern cotton growing area dramatically increased from 1997. Bt cotton acreage in Oklahoma, North Carolina, Texas, Arkansas, and Virginia increased; Missouri Bt cotton acreage did not markedly change. It is, therefore, premature to predict what the Bt cotton and Bt corn acreage will be in the future if restrictions are lifted in southern cotton growing regions.

Dr. Mike Caprio (Mississippi State University) has developed a corn-cotton ecosystem model for resistance evolution in *Helicoverpa zea* to Bt-endotoxins expressed in plants to examine the movement of CEW between corn, cotton, soybean, and other wild hosts. This work is ongoing and only preliminary results have been reported thus far. The model was designed to consider 400 independent fields including corn (Bt or non-Bt), Bt cotton, soybean (early or late), and wild host plants. The proportion of these crops among 400 fields is varied from replicate to replicate to determine the scenario that will lead to the quickest evolution of resistance. The model also considers movement associated with overwintering (two levels of movement, 30% and 90%, have been tested). The model assumes that corn is the preferred CEW host until day 50 of the growing season when it browns. Cotton is assumed to become attractive on day 40 and soybeans become attractive enough for oviposition on day 70. The model also assumes that there is no cross resistance between the toxins in Bt corn and Bt cotton and that the mortality of CEW genotypes is fixed at predetermined levels. Preliminary experiments with this model have been conducted, with a default of 160 fields of Bt cotton, 120 Bt corn/non-Bt corn, 80 sorghum, and 40 wild other hosts. These proportions were altered in subsequent trials.

Preliminary results of the Caprio model indicate that a high level of dispersal of CEW emerging from overwintering sites (90%) will contribute to a much faster rate of resistance development than lower post overwintering dispersal (30%) in all the field arrangements tested. In addition, in the presence of Bt cotton (160 fields), the ratio of Bt corn/non-Bt corn fields (120 total fields) becomes an important factor. As the ratio of non-Bt corn decreases relative to Bt corn, the time to resistance also decreases; meaning the less non-Bt corn planted as a refuge results in resistance developing faster. This effect was most pronounced when the percent of Bt to non-Bt corn exceeded 50%. This suggests that even without cross resistance as a variable, a sizable proportion of non-Bt corn (at least 50%) must be planted with Bt corn in Bt cotton growing regions to avoid the quick evolution of resistance.

Currently, the Caprio model is an example of what conclusions we can make based on current scientific findings. Caprio concluded from the results obtained thus far from this model that it is acceptable to plant some Bt corn in the mid-South but the proportion of Bt to non-Bt corn should not exceed 50%.

Current data provided by Monsanto give an unclear representation of CEW overwintering. Most of the CEW monitoring data are greater than 20 years old and do not represent enough sites to support a definitive "line" between the northern and southern cotton growing areas as Monsanto has indicated. Additional CEW overwintering data are necessary in the northern cotton growing area, especially in Arkansas, western Tennessee, and North Carolina, to substantiate the 20% unsprayed or 40% sprayed refuge option. Additional information should also be submitted regarding CEW flight distance to mating sites and CEW behavior.

Corn Growers Announce Agreement on Key Elements of Corn Insect Resistance Management (IRM) Program for 2000

January 29, 1999

ST. LOUIS, Jan. 28 /PRNewswire/ via NewsEdge Corporation – The National Corn Growers Association (NCGA) has announced that it and companies registering and selling the vast majority of Bt-improved corn hybrids have reached an agreement-in-principle on corn insect resistance management (IRM) for the year 2000. The goal is to present a consistent, unified program to preserve the technology that is practical for growers.

The agreement-in-principle includes five key elements with an accompanying document providing further details. This represents recommendations for the 2000 growing season and does not impact the 1999 production season.

"The message from NCGA members is clear – growers want a uniform plan they can easily adopt," said Tim Hume, NCGA Board member from Walsh, Colo. "They want it to be protective against insect resistance, but practical for their operations."

The agreement-in-principle, according to Hume, simply means that the companies producing the majority of Bt corn have agreed on key points necessary to move forward with a unified IRM plan.

The key elements are:

– One single protective and practical corn refuge requirement for the

primary corn-growing region (20%) and one corn refuge requirement for

the primary cotton-growing region (50%).

– A clear and consistent IRM grower agreement.

– Effective grower education programs.

– Appropriate surveys to track grower adoption.

– Continued insect susceptibility monitoring

The companies involved are Monsanto, Dekalb, Dow AgroSciences, Mycogen Seeds, Novartis Seeds and Pioneer Hi-Bred International. These companies represent the following Bt corn events: Bt11, MON810, DBT-418 and Event 176.

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Pest Management practices and treat only when corn borer densities

reach economic threshold levels. In cotton growing areas where

plantings of MON810 and BT11 are currently restricted, growers will be

required to plant a 20% refuge in the Northern cotton growing region

and a 50% refuge in the Southern cotton growing region. Regional

boundaries will be reviewed based upon the most current information

such as Bt cotton market penetration and corn earworm overwintering

survival, and adjusted accordingly.

II. IRM Agreement

– Growers will sign an agreement stipulating that they will follow the

IRM requirements detailed in Bt corn product grower guides supplied by

companies.

– Grower guides supplied by companies will include a uniform set of IRM

requirements to all corn growers purchasing Bt corn products

(Bt11, MON810, DBT-418, and Event 176 Bt Corn).

III. Grower Education

– It is clear that growers must understand the importance of Bt corn

insect resistance management. Therefore, a uniform set of IRM

requirements will be developed and communicated through individual seed

companies working with organizations such as: USEPA, USDA, NCGA, state

and county corn associations and land grant university extension

services.

– The companies recognize as well the critical importance of continuing

education to ensure IRM program implementation and are committed to

education programs.

IV. Grower Adoption of IRM Plan

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January 25, 1999

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Arlington, VA 22202

Attn: Mr. Mike Mendelsohn

Subject: YieldGard®, EPA Registration No. 524-489:
Request for extension of date to submit a 1998 Sales Report

Dear Mr. Mendelsohn:

As a condition of registration of Monsanto's YieldGard® plant pesticide product we are required to submit a report by January 31, 1999 of all sales of this product in 1998 by Monsanto or our distributors. We are requesting an extension of this submission date to February 15, 1999. This extension is requested to allow additional time to obtain the detailed county sales data and to format the data as required.

If you have any questions with regard to this request, please contact me at (314)737-6870, or contact me by e-mail at *karen.s.gustafson@monsanto.com*.

Sincerely,

Karen S. Gustafson
Associate Regulatory Affairs Manager

cc: Russ Schneider

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January 20, 1999

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Attn: Mr. Phil Hutton (#90)

Subject: Amendment of EPA Registration Number 524-489 for MON 810 YieldGard™ , *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn

Dear Mr. Hutton:

This letter is submitted to request the modification of specific terms and conditions associated with EPA Registration Number 524-489 for MON 810 YieldGard®, the *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production in corn. Monsanto specifically requests a modification of Item 12 of the terms and conditions that specifies that the combined sales of MON 810 YieldGard in the states and counties identified must not exceed 100,000 acres annually and that in these states and counties, the amount of YieldGard MON 810 corn sold must be no more than 5 percent of corn planted in any county with more than 1,000 acres of cotton. Monsanto requests the substitution of the 100,000 acre annual limitation, and the 5 percent sales limit per county, with the following refuge requirements and the addition of the following refuge requirements to the terms and conditions for the remainder of the U.S.

A. Effective January 25, 1999, in the following states and counties, Monsanto will require each grower who purchases YieldGard seed sign a grower agreement that mandates planting a minimum 50% refuge of non-Bt corn.

Alabama: all counties
Arkansas: *counties of Arkansas, Ashley, Bradley, Calhoun, Chicot, Clark, Cleveland, Columbia, Dallas, Desha, Drew, Garland, Grant, Hempstead,*

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Hot Spring, Howard, Jefferson, Lafayette, Lee, Lincoln, Little River, Lonoke, Miller, Monroe, Montgomery, Nevada, Oachita, Phillips, Pike, Polk, Prairie, Pulaski, Saline, Sevier, Union

Florida: all counties
Georgia: all counties
Louisiana: all counties
Mississippi: all counties
South Carolina: all counties
Texas: *all <u>except</u> the counties of Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Collingsworth, Cottle, Dallam, Deaf Smith, Donley, Floyd, Foard, Gray, Hale, Hall, Hansford, Hardeman, Hartley, Hemphill, Hutchinson, Lamb, Lipscomb, Moore, Motley, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Swisher, Wheeler, Wichita, Wilbarger*

B. Effective January 25, 1999, through June 30, 1999, in the following states and counties, Monsanto will require each grower who purchases YieldGard seed sign a grower agreement that mandates planting a minimum 20% refuge of non-Bt corn, unsprayed for target Lepidoptera insect control, or 40% refuge of non-Bt corn, sprayed for target Lepidoptera insect control.

Arkansas: *counties of Baxter, Benton, Bone, Carroll, Clay, Cleburne, Conway, Craighead, Crawford, Crittenden, Cross, Faulkner, Franklin, Fulton, Greene, Independence, Jackson, Johnson, Izard, Lawrence, Logan, Madison, Marion, Mississippi, Newton, Perry, Poinsett, Pope, Randolph, Scott, Searcy, Sebastian, Sharp, St. Francis, Stone, Van Buren, Washington, White, Woodruff, Yell*
Missouri: *bootheel counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard*
Oklahoma: *counties of Bryan, Caddo, Canadian, Garvin, Grady*
North Carolina: all counties
Tennessee: *counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, Tipton*
Texas: *Armstrong, Bailey, Briscoe, Carson, Castro, Childress, Collingsworth, Cottle,Deaf Smith, Donley, Floyd, Foard, Gray, Hale, Hall, Hardeman, Lamb, Motley, Oldham, Parmer, Potter, Randall, Swisher, Wheeler, Wichita, Wilbarger*
Virginia: *counties of Greensville, Isle of Wight, Northhampton, Southhampton, Sussex, Suffolk*

C. Through June 30, 1999, in all remaining states and counties, Monsanto will require each grower who purchases YieldGard seed sign a grower agreement that mandates planting a minimum 10% refuge of non-Bt corn, unsprayed for target Lepidoptera insect control, or 20% refuge of non-Bt corn, sprayed for target Lepidoptera insect control.

D. Effective July 1, 1999, in all states and counties, except those identified in A, above, Monsanto will require each grower who purchases YieldGard seed sign a grower agreement that mandates planting a minimum 20% refuge of non-Bt corn, unsprayed for target Lepidoptera insect control, or which refuge satisfies additional restrictions set forth in the Grower Guide if spraying is anticipated for target Lepidoptera insect control.

If there are any questions with regard to this request or the attached revised label, please call Dr. Russ Schneider at (202) 383-2866 or call me directly at (314) 737-5417.

Sincerely,

(for)

William P. Pilacinski, Ph.D.
Regulatory Affairs Manager

att: - Application for Pesticide, EPA Form 8570-1
- Certification with Respect to Citation of Data, EPA Form 8570-34
- revised YieldGard label, 3 pages

A

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number
~~108184~~
258604

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Monsanto/524-489	Phil Hutton	☑ None ☐ Restricted
4. Company/Product (Name)	PM# 90 92	
Monsanto/YieldGard Corn		

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198
☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 524-489
Product Name YieldGard Corn

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Request for removal of the annual 100,000 acre and 5 percent per county sales limits in cotton growing regions of the Southeastern US, and to define the refuge requirements throughout the US for MON 810 YieldGard Corn, EPA Registration no. 524-489 for Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) Plant Cells
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		

6. Manner in Which Label Is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☑ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider	Regulatory Director	(202)383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title	
William P. Pilacinski	Regulatory Affairs Manager	
4. Typed Name	5. Date	
William P. Pilacinski	January 21, 1999	15

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number
198184

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Monsanto/524-489	Phil Hutton	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Monsanto/YieldGard Corn	90	

5. Name and Address of Applicant *(Include ZIP Code)*

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. 524-489

Product Name YieldGard Corn

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in reponse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for removal of the annual 100,000 acre and 5 percent per county sales limits in cotton growing regions of the Southeastern US, and to define the refuge requirements throughout the US for MON 810 YieldGard Corn, EPA Registration no. 524-489 for Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) Plant Cells
• *tification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label Is Affixed to Product ☐ Uthograph ☐ Paper glued ☐ Stenciled ☑ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider	Regulatory Director	(202)383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
	Regulatory Affairs Manager	
4. Typed Name	**5. Date**	
William P. Pilacinski	January 21, 1999	16

Form approved. OMB No. 2070-0060. Approval expires 2-28-

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number
25E:04
~~198184~~

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Monsanto/ 524	Phil Hutton	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
Monsanto/YieldGard	18	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198
☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 524-489
Product Name YieldGard Corn

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Request for removal of the annual 100,000 acre and 5 percent per county sales limits in cotton growing regions of the Southeastern US, and to define the refuge requirements throughout the US for MON 810 YieldGard Corn, EPA Registration no. 524-489 for Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) Plant Cells
rtification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☑ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider	Regulatory Director	(202)383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
	Regulatory Affairs Manager	17
4. Typed Name: William P. Pilacinski	5. Date: January 19, 1999	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
258804

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

18

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number: 198169

Section I

1. Company/Product Number: Monsanto / 524-489
2. EPA Product Manager: Phil Rutton
3. Proposed Classification: ☐ None ☐ Restricted
4. Company/Product (Name): Monsanto/ Bacillus thuringiensis
PM#: 18 74
5. Name and Address of Applicant *(Include ZIP Code)*:
Monsanto Company
700 14th Street, N.W., #1100
Washington, D.C. 20005
☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☒ Amendment - Explain below
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application 67616 9
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission to amend label for the Registration for the Plant Pesticide Bacillus thuringiensis Insect Control Protein (CryIA(b)) in Corn (524-489).

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No 92	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) Plant cells
* *Certification must be submitted.*	If "Yes," Unit Package wgt. 5 No. per container /	If "Yes," Package wgt. No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container
4. Size(s) of Retail Container
5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☒ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulation Director	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Regulatory Affairs Manager	Kenta A. Croon, Ph.D.	October 1, 1997

19

EPA Form 8570-1 (Rev. 12-90) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant copy

MONSANTO
Food · Health · Hope

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
http://www.monsanto.com

September 16, 1998

Registration Division (H7505C)
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Mr. Phil Hutton (#90)

Subject: Amendment of EPA Registration Number 524-489 for MON 810 YieldGard™ , *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn

Dear Mr. Hutton:

This submission is made to request the modification of specific terms and conditions associated with EPA Registration Number 524-489 for MON 810 YieldGard®, the *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production in corn. Monsanto specifically requests a modification of Item 12 of the terms and conditions that specifies that the combined sales of MON 810 YieldGard in the states and counties identified must not exceed 100,000 acres annually and that in these states and counties, the amount of YieldGard MON 810 corn sold must be no more than 5 percent of corn planted in any county with more than 1,000 acres of cotton.

Monsanto requests the substitution of the 100,000 acre annual limitation, and the 5 percent sales limit per county, with the following on-farm refuge beginning with the 1999 growing season:

1. In an area defined within the submission as the **Southern cotton growing region**, including southern Texas, southern Arkansas, Louisiana, Mississippi, Alabama, Georgia, South Carolina, and Florida, growers will be required to plant a minimum of 50 percent of their corn acreage to non-*B.t.* corn. The non-*B.t.* corn refuge may be treated as needed with non-*B.t.* insecticides to control lepidopteran insect pests.

2. In an area defined within the submission as the **Northern cotton growing region**, including northern Texas (but not 10 Panhandle counties), northern Arkansas, North Carolina and currently restricted counties within Missouri, Oklahoma, Tennessee, and Virginia, growers will be required to maintain a

corn.

The justification for this request is discussed in greater detail within this document.

If there are any questions with regard to this submission, please call Dr. Russ Schneider at (202) 383-2866 or call me directly at (314) 737-5417.

Sincerely,

William P. Pilacinski, Ph.D.
Regulatory Affairs Manager

MONSANTO

Food · Health · Hope

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
http://www.monsanto.com

September 16, 1998

Registration Division (H7505C)
Biopesticide and Pollution Prevention Division
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Document Processing Desk
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
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Attn: Mr. Phil Hutton (#90)

Subject: Amendment of EPA Registration Number 524-489 for MON 810 YieldGard™ , *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn

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Monsanto requests the substitution of the 100,000 acre annual limitation, and the 5 percent sales limit per county, with the following on-farm refuge beginning with the 1999 growing season:

1. In an area defined within the submission as the **Southern cotton growing region**, including southern Texas, southern Arkansas, Louisiana, Mississippi, Alabama, Georgia, South Carolina, and Florida, growers will be required to plant a minimum of 50 percent of their corn acreage to non-*B.t.* corn. The non-*B.t.* corn refuge may be treated as needed with non-*B.t.* insecticides to control lepidopteran insect pests.

2. In an area defined within the submission as the **Northern cotton growing region**, including northern Texas (but not 10 Panhandle counties), northern Arkansas, North Carolina and currently restricted counties within Missouri, Oklahoma, Tennessee, and Virginia, growers will be required to maintain a

minimum on-farm refuge of 20 percent unsprayed or 40 percent sprayed non-*B.t.* corn.

The justification for this request is discussed in greater detail within this document.

If there are any questions with regard to this submission, please call Dr. Russ Schneider at (202) 383-2866 or call me directly at (314) 737-5417.

Sincerely,

William P. Pilacinski, Ph.D.
Regulatory Affairs Manager

H

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-9

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
- ☑ Amendment
- ☐ Other

OPP Identifier Number
~~100100~~ 525582

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Monsanto/ 524 - 489	Phil Hutton	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Monsanto/YieldGard	~~18~~ 92	
5. Name and Address of Applicant *(Include ZIP Code)*	**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:	
Monsanto Company 700 Chesterfield Parkway No. St. Louis, MO 63198	EPA Reg. No. 524-489	
☐ *Check if this is a new address*	Product Name YieldGard Corn	

Section - II

- ☑ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☐ Final printed labels in repsonse to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request for Removal of the Annual 100,00 Acre and 5 Percent Per County Sales Limits on MON 810 YieldGard Corn in Cotton Growing Regions of the Southeastern U.S., EPA Registration no. 524-489 for Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) Plant Cells
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☑ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider	Regulatory Director	(202)383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	3. Title	6. Date Application Received (Stamped)
William P. Pilacinski	Regulatory Affairs Manager	24
4. Typed Name: William P. Pilacinski	5. Date: September 16, 1998	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
251582

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

25

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Request to Amend the Registration for the Plant Pesticide Product, YieldGard™, *Bacillus thuringiensis* CryIA(b) Delta-endotoxin and the Genetic Material Necessary for Its Production in Corn

EPA Registration No. 524-489

TRANSMITTAL DATE

September 16, 1998

LIST OF SUBMITTED DOCUMENTS

Volume 1: "Request for Removal of the Annual 100,000 Acre and 5 Percent Per County Sales Limits on MON 810 YieldGard Corn in Cotton Growing Regions of the Southeasten U.S.", an unpublished report prepared by Monsanto Company.

COMPANY OFFICIAL: _____ 16 Sep 98

William P. Pilacinski, Ph.D Date
Regulatory Affairs Manager

COMPANY NAME: MONSANTO COMPANY

COMPANY CONTACT: Dr. Russell Schneider (202) 383-2866

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
William P. Pilacinski, Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198	524-489
Active Ingredient(s) and/or representative test compound(s) Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its prod. in con	Date January 19, 1999
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name YieldGard Corn

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☑ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
William P. Pilacinski	19 January 1999	William P. Pilacinski, Ph.D., Regulatory Affairs Mgr.

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

EPA Reg No. 524-489, Vol. 2

Page _____ is not included in this copy.

Pages 28 through 30 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

✓ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Request to Amend the Registration for the Plant Pesticide Product, YieldGard™, *Bacillus thuringiensis* CryIA(b) Delta-endotoxin and the Genetic Material Necessary for Its Production in Corn

EPA Registration No. 524-489

TRANSMITTAL DATE

September 16, 1998

LIST OF SUBMITTED DOCUMENTS

Volume 1: "Request for Removal of the Annual 100,000 Acre and 5 Percent Per County Sales Limits on MON 810 YieldGard Corn in Cotton Growing Regions of the Southeasten U.S.", an unpublished report prepared by Monsanto Company.

COMPANY OFFICIAL: _____ 16 Sep 98

William P. Pilacinski, Ph.D Date
Regulatory Affairs Manager

COMPANY NAME: MONSANTO COMPANY

COMPANY CONTACT: Dr. Russell Schneider (202) 383-2866

31

Summary Title

Request for Removal of the Annual 100,000 Acre and 5 Percent Per County Sales Limits on MON 810 YieldGard Corn in Cotton Growing Regions of the Southeastern U.S.

Data Requirement

Request to Amend the Registration for the Plant Pesticide, YieldGard™, *Bacillus thuringiensis* CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn (EPA Reg. No. 524-489)

Registrant Submitting Date

September 16, 1998

Registrant Submitting

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

98-374E

Volume 1 of 1

32

EPA Reg No. 524-489, Vol. 2

Page _____ is not included in this copy.

Pages 33 through 89 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 10 1998

Dr. William P. Pilacinski
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear Dr. Pilacinski:

Subject: Request for Extension of Date to Submit a Draft Plan for Structured Refuge
Your Letter of July 30, 1998
EPA File Symbol 524-489

In order to allow additional time to analyze data from predictive models and grower compliance with refuge requirements, we hereby grant an extension for submission of your draft plan for structured refuge from August 9, 1998 to August 31, 1998.

Sincerely,

Janet L. Andersen

Janet L. Andersen, Director
Biopesticides and Pollution
Prevention Division (7511C)

CONCURRENCES								
SYMBOL	7511C							
SURNAME								90
DATE	8/4/98							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

MONSANTO

Food · Health · Hope

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
http://www.monsanto.com

30 July 1998

Office of Pesticide Programs - H7505C
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Document Processing Desk
Room 266 A, Crystal Mall # 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Mr. Mike Mendelsohn

Subject: YieldGard™ , EPA Registration No. 524-489: Request for extension of date to submit a draft plan for "structured" refugia.

Dear Mr. Mendelsohn:

As a condition of registration of Monsanto's YieldGard plant pesticide product, we are required to submit a draft plan for "structured" refugia by 9 August 1998. We are requesting an extension of this submission date to 31 August 1998. This extension is requested to allow additional time to analyze data recently obtained from predictive models for the development of Bt resistance by European corn borer and corn earworm, as well as new studies on grower compliance with refuge requirements.

If you have any questions with regard to this request, please call me at (314) 737-5417, or contact me by e-mail at *william.p.pilacinski@monsanto.com.*

Sincerely,

William P. Pilacinski, Ph.D.
Regulatory Affairs Manager

cc: Russ Schneider
mydoc\epa\8jul30mm.doc

91

Janet Andersen
07/31/98 11:22 AM

To: Mike Mendelsohn/DC/USEPA/US@EPA
cc: Phil Hutton@EPA
Subject: Re: Extension of Submission Date for Preliminary IRM PLan

Phil and I talked about this briefly. We need a letter, not a email note, with justification for the extension. The letter goes on the docket.

YieldGard™

Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* control protein as expressed by the *cryIA(b)* gene in corn cells.

Active Ingredient:

Bacillus thuringiensis CryIA(b) delta endotoxin and the genetic material necessary for its production in corn	0.023 - 0.029%*

*Percentage of total protein on a dry weight basis.

Keep Out of Reach of Children

CAUTION

EPA REGISTRATION NUMBER 524-489

EPA ESTABLISHMENT NUMBER 524-MO-002

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

ACCEPTED
with COMMENTS
In EPA Letter Dated

FEB 6 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 524-489

Directions for Use:

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Monsanto will ensure that in the combined states of Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Virginia (only the counties of Greensville, Isle of Wight, Northhampton, Southhampton, Sussex, and Suffolk), Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, and Stoddard), Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, and Tipton) and Texas (with exception of the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts and Carson) that the combined sale of this plant pesticide will not exceed the amounts required to plant 100,000 acres per anum. Further, Monsanto will ensure that for the states and counties listed above that the amount sold will result in no more than 5% of the corn planted in any county with more than 1,000 acres of cotton. Monsanto will report all sales of this product by Monsanto or its distributors annually to the EPA no later than January 31st of the following year.

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Corn has been transformed to express the CryIA(b) form of the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin protein for the control or suppression of the following lepidopteran corn insect pests:

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant pesticide must be accompanied by a Grower Guide which instructs growers to read the Grower Guide prior to planting for information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* delta-endotoxin protein are planted.

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

December 19, 1997

Registration Division (H7505C)
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Mr. Phil Hutton

Subject: Amendment of EPA Registration Number 524-489 for the *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn (YieldGard®).

Dear Mr. Hutton:

This submission is made to request the modification of specific terms and conditions associated with EPA Registration Number 524-489 for the *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn (YieldGard® Insect Protected Corn™).

Monsanto requests the removal of the following corn producing counties in the Texas panhandle from areas of the southern U.S. in which the combined sale of this plant pesticide will not exceed the amounts required to plant 100,000 acres per anum.

Dallam	Ochiltree	Moore	Carson
Sherman	Lipscomb	Hutchinson	
Hansford	Hartley	Roberts	

This is requested as these contiguous counties in the panhandle of Texas constitute an area in which corn is grown and cotton is not grown as documented in USDA National Agricultural Statistics Service (USDA NASS) records.

In coordination with this registration amendment request, Monsanto is also submitting a letter and accompanying registration amendment to the Agency citing the fact that cotton has not historically been produced in these counties due to environmental limitations and as a result, Monsanto will not sell Bollgard® cotton in these counties.

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The YieldGard label enclosed also reflects the changes requested by Monsanto in October and currently in review at the Agency. These include the addition of certain lepidopteran insect pests to the list of species controlled or suppressed and spelling corrections to the original list of counties.

If there are any questions with regard to this submission, please call Dr. Russ Schneider at (202) 783-2460 or call me directly at (314) 737-7488.

Sincerely,

Kent A.Croon, Ph.D.
Regulatory Affairs Manager

A B

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [XX] Amendment
- [ ] Other

OPP Identifier Number: 198171

Section I

1. Company/Product Number: 524-489
2. EPA Product Manager: PHIL HUTTON
3. Proposed Classification: [ ] None [ ] Restricted
4. Company/Product (Name): MONSANTO/YIELDGARD MON810
   PM#: 92
5. Name and Address of Applicant *(Include ZIP Code)*:
   MONSANTO COMPANY
   700 14TH STREET NW, #1100
   WASHINGTON, D.C. 20005
   [ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

RECEIVED
DEC 29 1997
OPP/BPPD

Section II

- [XX] Amendment - Explain below
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

LABEL AMENDED TO INCLUDE PRODUCT USE IN TEN COUNTIES IN THE PANHANDLE OF TEXAS

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [XX] No	[ ] Yes [XX] No	[ ] Yes [XX] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [XX] Other (Specify) PLANT CELLS
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) of Retail Container:
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
RUSSELL P. SCHNEIDER	AGRICULTURAL REGULATION DIRECTOR	202-783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped): 97

2. Signature: Kent A. Croon
3. Title: REGULATORY AFFAIRS MANAGER
4. Typed Name: KENT A. CROON, PH.D.
5. Date: DECEMBER 18, 1997

FEB 6 1998

300 | 55[illegible]166
18

Dr. Keith Reding
Regulatory Affairs Manager
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear Dr. Reding:

Subject: Label Amendment Applications to Modify the Terms and Conditions of the Subject Registrations to 1) Allow Unlimited Use of Yieldgard/MON810 Bt Corn in Ten Counties of the Texas Panhandle and to 2) Prohibit the Use of Bt Cotton in the Same Ten Counties EPA Registration Nos. 524-489 & 524-478

The amendment for Yieldgard, EPA Reg. No. 524-489, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable and the term and condition restricting commercial sale listed as item 12 in the notice of registration is modified to read as follows:

Monsanto will ensure that in the combined states of Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (with the exception of the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartey, Moore, Hutchinson, Roberts and Carson) ,Virginia (only the counties of Greensville, Isle of Wight, Northampton, Southampton, Sussex, Suffolk) and Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard) that the combined sale of this plant-pesticide in all the above states will not exceed the amounts required to plant 100,000 acres per anum. Further, Monsanto will ensure that for the states and counties listed above that the amount sold will result in no more than 5% of the corn planted in any county with more than 1000 acres of cotton. Per item 9 of the notice of registration Monsanto will report all sales of this product by Monsanto or its distributors annually to EPA no later than January 31st of the following year.

A stamped copy of the label and a copy of our recent resistance management review are enclosed for your records. Submit five (5) copies of the final printed labeling.

The amendment for EPA Reg. No. 524-478, Bollgard, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the following comments and the term and condition restricting commercial

SYMBOL								
SURNAME	Mendez	Nelson	Hutton					
DATE	2/4/98	2/4/98	2/4/98					98

sale is modified to read:

In Florida do not plant south of Tampa, (Florida Route 60). Not for commercial sale or use in Hawaii. Test plots or breeding nurseries established in Hawaii must be surrounded by either 12 border rows of non-transgenic cotton if the plot size is less than 10 acres or 24 border rows if the plot is over 10 acres, and must not be planted within 1/4 mile of *Gossypium tomentosum*. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

1) Modify the ingredient statement on the product label by changing "*Bacillus thuringiensis* subsp.*kurstaki* delta endotoxin as produced by the CryIA(c) gene and its controlling sequences in cotton" to read "*Bacillus thuringiensis* subsp.*kurstaki* CryIA(c) delta endotoxin and the genetic material necessary for its production in cotton".

2) Modify the label by adding the EPA establishment number(s) to the label.

3) Modify the label by adding the KEEP OUT OF REACH OF CHILDREN statement and immediately below it the signal word CAUTION on the front panel of the label after the ingredient statement.

4) This amendment restricting the sale of Bt cotton in ten counties of the Texas Pan Handle must be implemented during the 1998 growing season.

Your release of Bt cotton into commerce with the amended grower guide constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Sincerely,

Janet L. Andersen

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Division (7511W)

Enclosures

CONCURRENCES								
SYMBOL				2				
SURNAME								99
DATE								

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REVIEWER: MENDELSOHN

(ASSIGNED BY: DON.)

EPA REG./FILE SYMBOL 524-489

ACTION CODE 300

SUBMISSION BARCODE _____ Amendment

Date on Application 12-18-97

EPA Received Date 12-19-97

M Received Date 12-29-97

Assigned in PRAT YES____ NO____

Completed by: S. Diana Hudson Date_____

FINAL ACTION

Response Code_____

Response Date: / /

MOS: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes____ No____

Restricted Use: Yes____ No____

Manufacturing Use: Yes____ No____

Exclusive Use: Yes____ No____

100

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

12/22/97

RUSSELL P SCHNEIDER
MONSANTO CO
700 14TH ST, N.W. SUITE 1100
WASHINGTON DC 20005

PRODUCT NAME: YIELDGARD MON810
COMPANY NAME: MONSANTO CO
OPP IDENTIFICATION NUMBER: 198171
EPA REGISTRATION NUMBER: 524-489
EPA RECEIPT DATE: 12/19/97

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Phil Hutton, Product Manager 92, at (703) 308-8260.

Sincerely,

J Price

Front End Processing Staff
Information Services Branch
Program Management and Support Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 26, 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

TO: Michael L. Mendelsohn
Regulatory Action Leader
Biopesticides and Pollution Prevention Division (7511W)

FROM: Alan H. Reynolds, Entomologist
Biopesticides and Pollution Prevention Division (7511W)

and

Sharlene R. Matten, Ph.D., Biologist
Biopesticides and Pollution Prevention Division (7511W)

SUBJECT: Review of Monsanto's proposed label amendment to end restrictions on the sale and use of MON 810 Bt corn (File Symbol No. 524-489; DP Barcode No. D242339) in the Texas High Plains region.

Action Requested

BPPD has been asked to review Monsanto's proposed amendment to request the unrestricted use of the plant-pesticide *Bacillus thuringiensis* CryIA(b) delta endotoxin and the genetic material necessary for its production [EPA Reg. No. 524-489] (MON 810 Bt corn) in the High Plains region of Texas: the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson. In addition, Monsanto proposes to amend its Bollgard® cotton registration of the Bt plant-pesticide CryIA(c) delta endotoxin and the genetic material necessary for its production [EPA Reg. No. 524-478] to suspend the sale and distribution of Bt cotton in these same Texas counties.

Conclusions

Upon review, the unrestricted use of MON 810 Bt corn in the Texas High Plains counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson should not significantly increase the risk of resistance developing in corn earworm (CEW, *Heliothis zea*) to Bt CryIA toxins. The counties in question have negligible, if any, cotton acreage and is reasonably isolated from areas of high cotton production to the south. In addition, Monsanto will not allow the sale or distribution any Bt cotton in these counties, further reducing the resistance risk. It should be noted that counties in neighboring states also in close

proximity to the High Plains area in Texas are not presently restricted for Bt corn use and have negligible, if any, cotton acreage.

CEW is a highly mobile pest that typically moves from corn to cotton once field corn begins to senesce, creating a resistance risk if Bt products are used in corn and/or cotton. However, in this case, such risk is mitigated by the lack of cotton production in the immediate and neighboring counties to the Texas High Plains region. This risk could also be further mitigated by the adoption of a refuge strategy.

Background Information

Biology of Corn Earworm

CEW has a wide host range that includes corn, cotton, alfalfa, sorghum, tobacco, and numerous other grasses and vegetable crops. The insect has multiple generations throughout most of the United States with as many as 3-6 in southern cotton growing regions. First and second generation CEW attack corn, feeding on developing plant tissues. Second generation CEW typically feed on silks and kernels in developing ears. Second generation adults will leave browning corn fields near the end of the season and move to alternate hosts, including cotton where another several generations may occur.

CEW is highly mobile, and has been observed to migrate distances over 160 km. Many long distance flights occur in the Spring, when CEW recolonizes Northern areas not suitable for overwintering. However, research has shown that most adult flight activity during the growing season is more localized than migratory. The presence of suitable alternate hosts at the conclusion of the field corn season may help to deter long migrations.

Bt Corn

To date, the EPA has registered five Bt corn products expressing the CryIA(b) or CryIA(c) toxins. EPA imposed restrictions on the number of acres allowed in the South on Bt corn hybrids expressing the Bt delta endotoxin in silks and kernels. At present this would include events MON810, BT11 (Northrup-King/Novartis Seeds), DBT418 (DEKALB Genetics Corp.) derived hybrids, but not Event 176 (Ciba/Novartis Seeds, Mycogen Corp.) derived hybrids. A total of 200,000 acres was allowed in the South: 100,000 acres each for MON810 and BT11-derived Bt corn hybrids. Event 176 CryIA(b)-expressing corn was not restricted because it has only trace (<8 ppb) levels of the delta endotoxin in silks and kernels and is not expected to select for second generation CEW resistance. In addition to sales restrictions, research data and model development were required on all the Bt hybrids registered to evaluate the potential impact of Bt corn on Bt resistance management programs in areas growing corn and cotton.

Silk and kernel expression in Bt corn hybrids will likely increase the selection for CEW resistance especially in cotton-growing areas. If there is silk expression of the CryIA(b)/CryIA(c) delta endotoxin at sufficient levels to select for resistant CEW, then resistant CEW could move from Bt corn to cotton/Bt cotton, posing potentially significant problems in cotton or Bt cotton or

in other crops affected by CEW. Where corn and cotton acres are in close proximity, there will be migration of second generation CEW from silk-stage Bt corn to cotton (including Bt cotton) and other crops. In the southeastern U.S., virtually all second generation CEW funnel through corn where they complete development on the ear of this preferred host. Selection for CEW resistance could be accelerated if Bt corn hybrids became widely adopted in the South if adequate resistance management was not adopted. In the South, there are 3 to 6 CEW generations and in the North, there are 1 or 2 generations. Thus, CEW in the South are potentially subject to higher levels of exposure to the Bt delta endotoxin than CEW in the North. Although CEW only overwinter in the South, the development of CEW resistance to Bt in the North is also a concern. The major source of CEW in the northern corn belt is adults migrating from the southern states each year. Should CEW resistance to Bt toxins develop in the South, it could be equally damaging in the northern states growing Bt corn each season. In the South, there would be a higher selection pressure in areas in which Bt corn and Bt cotton are in close proximity and in areas in which Bt microbial pesticide products are used. Resistant CEW could lead to the failure of Bt microbial pesticides used on cotton and other crops or to the failure of Bt cotton, Bt corn, and other crops both in the South and in the North for control of CEW.

Review of Proposed Amendment

Monsanto has proposed to amend its registration to request the use of MON 810 Bt corn in the Texas High Plains counties (Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman) while simultaneously suspending the sale and distribution of Bt cotton (Bollgard®) in these counties. Bt corn planted in these counties would be unrestricted and not subject to the 200,000 acre limit imposed for major cotton growing areas in the South.

According to data provided by Monsanto, there is no cotton production in the counties listed above. In addition, the surrounding Texas counties of Armstrong, Gray, Hemphill, Oldham, Potter, and Randall also have no cotton production and provide a buffer between the proposed Bt corn region and cotton growing counties to the South. Neighboring states (Oklahoma and New Mexico) also have no significant cotton acreage in counties that border the High Plains region. There is also some indication that the high cost of planting Bt cotton has prevented its widespread use in the cotton growing counties south of the High Plains. This spatial isolation, coupled with Monsanto's plan to prohibit Bt cotton use in the High Plains counties requested, should mitigate the risk of resistant CEW moving from Bt corn to cotton.

It should also be noted that many counties in surrounding states (Oklahoma and New Mexico) have no restrictions for the use of Bt corn. Many of these areas are actually in closer proximity to the cotton growing regions of Texas than the High Plains region in North Texas.

As discussed previously, CEW is highly mobile and capable of long migrations. Therefore, there will always be a risk of CEW movement from Bt corn to cotton where additional selection pressure may be encountered (from Bt crops or Bt microbial pesticide applications). However, much of the flight activity of CEW in midseason is localized and not likely to result in long

migrations given the geographic isolation of the proposed Bt corn region in the High Plains.

Although there are currently no EPA mandated requirements for refugia with Bt corn, the use of a refuge has the potential to delay the development of resistance in pest insects. According to the terms of its registration, Monsanto must submit a draft refuge strategy to the Agency by August 9, 1998 and a final refuge strategy by January 31, 1999. Monsanto must implement an EPA approved "structured" refuge plan or an EPA approved alternative resistance management plan by no later than April 1, 2001. Monsanto is also required to discuss the development and implementation of the refuge plan and alternative resistance management practices with EPA throughout this time frame. For MON810 Bt corn, Monsanto has presently mandated refuge requirements (either a 5% unsprayed or 20% sprayed non Bt corn) through its Grower Agreements. These refuge requirements should also help to mitigate the resistance risk of CEW in corn and cotton by reducing the number of resistant individuals produced in Bt corn. Monsanto should keep these refuge requirements in place for any Bt corn distributed in the Texas High Plains region.

In the case of a highly mobile pest such as CEW, an alternate crop refuge may be of additional value. Once field corn browns, CEW move out of corn fields to find other suitable hosts which can include cotton. The presence of an acceptable alternate crop or a non-corn refuge may serve to keep CEW in the local vicinity and deter longer migrations to cotton regions. An example of such an alternate crop refuge could be alfalfa, a crop that persists beyond the field corn season and is a common overwintering habitat for CEW. However, more data and research is still needed to fully evaluate the potential benefits of alternate host refuges.

Biopesticides and Pollution Prevention Division

FAX

NUMBER OF PAGES: 5

DATE: February 12, 1998

TO: Tom Sell, Staffer
U.S. House of Representatives

Fax 202-225-9615

FROM: Mike Mendelsohn, Microbiologist
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency
401 M St, S.W., Washington, D.C. 20460
Phone (703) 308-8715
FAX (703) 308-7026
email: mendelsohn.mike@epamail.epa.gov

MESSAGE:

Per your request, I have attached copies of the approved labels for Monsanto's Bt corn and Bt cotton regarding changes in the Texas panhandle. I hope this helps.

Regards,

Mike Mendelsohn

MESSAGE CONFIRMATION

FEB-12 13:21 THU

FAX NUMBER : 703-308-7026

NAME : BIOPESTICIDES

FAX NUMBER : 92022259615

PAGE : 05

ELAPSED TIME : 02'13"

MODE : G3 STD

RESULTS : O.K

Author: ROBYN ROSE at DCOPP12
Date: 01/06/98 04:17 PM
Priority: Normal
TO: Mike Mendelsohn
Subject: Re: Correct County Names for Bt Corn
---------- Message Contents ----------

In Virginia: "Isle of Wright" should be "Isle of Wight" and "Greenville" should be "Greensville". In Missouri: "Dunkin" should be "Dunklin." The label amendment was never completed because they will be amending it again shortly.

---------- Reply Separator ----------
Subject: Correct County Names for Bt Corn
Author: Mike Mendelsohn at DCOPP12
Date: 01/06/98 03:59 PM

Robyn,

Could you send me an email with the corrected county names for those that were incorrect? Thanks.

Mike Mendelsohn

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

October 7, 1997

Superseded by 11/18/97 amendment

Registration Division (H7505C)
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Mr. Phil Hutton

Subject: Amendment of EPA Registration Number 524-489 for the *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn (YieldGard™).

Dear Mr. Hutton:

This submission is made to request the amendment of the label associated with EPA Registration Number 524-489 for the *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn (YieldGard™).

The YieldGard label (5 original copies) which accompanies this request reflects the following modifications:

After consulting with state officials, certain county designations on page 1 of 2 have been corrected which include for the state of Virginia the substitution of "Isle of Wight" for "Isle of Wright", "Greensville" for "Greenville" and in Missouri "Dunklin" for "Dunkin". In Tennessee, Monsanto requests the addition of Dyer county to the list of counties under the geographic limitation as the county is a significant cotton producing county and this would provide consistency in YieldGard product usage with adjacent counties within this state.

On page 2 of the label (page 2 of 2), the list of lepidopteran insect pests has been modified to reflect the addition of southern cornstalk borer (*Diatraea crambidoides*), fall armyworm (*Spodoptera frugiperda*), and stalk borer (*Papaipema nebris*) to the list of species. Addition of these species to the Yieldgard label is consistent with ongoing insect resistance management (IRM) research as identified in the terms and conditions of the registration (524-489) items 11.e and 11.f.

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The language on page 2 of 2 regarding the general lack of need for additional insecticide applications and instructions as to the use of the Grower Guide has been condensed into paragraph form.

If there are any questions with regard to this submission, please call Dr. Russ Schneider at (202) 383-2866 or call me directly at (314) 737-7488.

Sincerely,

Kent A.Croon, Ph.D.
Regulatory Affairs Manager

Author: KENT.A.CROON@monsanto.com at IN
Date: 12/03/97 11:08 PM
Priority: Normal
BCC: robyn rose at DCOPP12
TO: rose.robyn@epamail.epa.gov at IN
CC: RUSSELL.P.SCHNEIDER@monsanto.com at IN
CC: KENT.A.CROON@monsanto.com at IN
Subject: YieldGard Product Label Change
---------- Message Contents ----------

From KENT.A.CROON@monsanto.com
X-Envelope-From: KENT.A.CROON@monsanto.com
Received: from gatekeeper.monsanto.com by epamail.epa.gov (PMDF V5.1-8 #22480)
with SMTP id <0EKN2MAKS00GO7@epamail.epa.gov> for
robyn_rose_at_dcopp12@lancelot.rtptok.epa.gov; Wed,
3 Dec 1997 19:27:47 -0500 (EST)
Received: by gatekeeper.monsanto.com; id LAA25594; Wed,
03 Dec 1997 11:26:05 -0600
Received: from nplxsl01.monsanto.com(164.144.252.39) by gatekeeper.monsanto.com
via smap (3.2) id xma024935; Wed, 03 Dec 1997 11:25:45 -0600
Received: by nplxsl01.monsanto.com (NPlex 1.3.167); Wed,
03 Dec 1997 11:25:44 -0600
Date: Wed, 03 Dec 1997 11:21:32 -0600
From: KENT.A.CROON@monsanto.com
Subject: YieldGard Product Label Change
To: rose.robyn@epamail.epa.gov
Cc: RUSSELL.P.SCHNEIDER@monsanto.com, KENT.A.CROON@monsanto.com
Message-id: <"1203172539-YieldGard Product Label Change"@MHS>
MIME-version: 1.0
Content-type: text/plain; charset=iso-8859-1
Content-transfer-encoding: 7bit

Thank you for the phone message which you left with me on Monday, December 1 regarding our request to amend the label for our YieldGard corn product expressing the B.t. Cry1Ab protein.

I am sending this message to confirm that as requested in our October 10, 1997 correspondance and accompanying revised label, Monsanto requests modifications to (1) correct certain county designations for Virginia (Isle of Wight, Greensville) and Missouri (Dunklin), (2) add certain insect species to the label and (3) condense wording regarding insecticide applications and grower guide instructions into paragraph form.

Monsanto does not request at this time the addition or deletion of additional counties, including Dyer County, Tennessee, from the YieldGard label. I personally apologize for any confusion caused by the late substitution of YieldGard labels.

Kent Croon, Ph.D.
Regulatory Affairs Manager

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EPA Reg No. 524-489, Vol. 2

Page _____ is not included in this copy.

Pages 112 through 113 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

✓ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

United States Environmental Protection Agency
Washington, DC 20460

EPA Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address	EPA File Symbol/Registration Number
Monsanto Company 700 14th Street, N.W., #1100 Washington, D.C. 20005	524-489
	Product Name: Bacillus thuringiensis CryIA(b) as expressed in corn
	Date of Application: October 1, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of apropval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

   | | I am the original submitter*; or

   | | I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

   a. |X| I am the original data submitter*; or

      | | I have obtained the written permission of the original data submitter to cite that study*; or

   b. | | I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

      | | All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

      | | Those companies that have submitted the studies which I have cited (Selective method*).

   * A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature	Name and Title	Date
[signature]	Kent A. Croon Regulatory Affairs Manager	October 1, 1997

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date
[signature]	Kent A. Croon Regulatory Affairs Manager	October 1, 1997

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EPA Form 8570-29 (Rev-7-91)

A B

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number: 198169

Section I

1. Company/Product Number: Monsanto / 524-489
2. EPA Product Manager: Phil Hutton
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Monsanto / Bacillus thuringiensis
PM# ~~18~~ 92
5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
700 14th Street, N.W., #1100
Washington, D.C. 20005
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No._____
Product Name_____

Section II

- [X] Amendment - Explain below
- [ ] Resubmission in response to Agency letter dated_____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated_____
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission to amend label for the Registration for the Plant Pesticide Bacillus thuringiensis Insect Control Protein (CryIA(b)) in Corn (524-489).

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [X] Other (Specify) Plant cells
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) of Retail Container
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [X] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulation Director	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
	Regulatory Affairs Manager	
4. Typed Name	5. Date	
Kent A. Croon, Ph.D.	October 1, 1997	115

NOTE TO FILE
12/16/97

The following counties were spelled incorrectly on the label and amended. In Virginia "Isle of Wight" was substituted for "Isle of Wright" and "Greensville" for "Greenville". In Missouri "Dunklin" was substituted for "Dunkin". Correct spellings were verified using county listings on the internet and the State Farm Road Atlas.

Robyn L. Rose

EPA Reg. No. 524-489

Page _____ is not included in this copy.

Pages 117 through 118 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

✓ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

10/10/97

RUSSELL P SCHNEIDER
MONSANTO CO
700 14TH ST, N.W. SUITE 1100
WASHINGTON DC 20005

PRODUCT NAME: BACILLUS THURINGIENSIS
COMPANY NAME: MONSANTO CO
OPP IDENTIFICATION NUMBER: 198169
EPA REGISTRATION NUMBER: 524-489
EPA RECEIPT DATE: 10/09/97

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Phil Hutton, Product Manager 92, at (703) 308-8260.

Sincerely,

J. White

Front End Processing Staff
Information Services Branch
Program Management and Support Division

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Appl # 19816 9

APPLICATION FOR AMENDMENT

WITH DATA			NO DATA		
	INIT.	DATE		INIT	DATE
FEU			FEU	FEU	10-10-97
SIG (DATA)			PM	92	
PM					

120